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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,513	06/20/2000	Alan Collmer	19603/3306 (CRF D-2136B)	5828

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Michael L Goldman
Nixon Peabody LLP
Clinton Square PO Box 31051
Rochester, NY 14603

EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	24

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,513	COLLMER ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-10* is/are rejected.

7)☒ Claim(s) *2 and 3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 MArch 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 July 2003 has been entered.

2. The amendments to the specification and the claims 18 July 2003, have been entered. Claims 1-10 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 June 2002. Applicant's arguments filed 18 April 2003 have been fully considered but they are not persuasive.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "a DNA molecule from a source other than *Pseudomonas syringae* pv *tomato*".

Applicant points to hybridization data in Examples 5 and 10 in which HrpW hybridizes to a band of DNA in genomic DNA blots from other *P. syringae* strains to show they were in possession of DNAs from sources other than *P.s.* pv *tomato* (response pg 6).

This is not found persuasive because there is no support for the idea that the claimed invention is from a *P. syringae* strain other than *P.s.* pv *tomato*. The specification claims all nucleic acids that hybridize to SEQ ID NO:1 and that encode a hypersensitive reponse elicitor other than those from various *Erwinia* species or *P.s.* pv *syringae* (see paragraph spanning pg 10-11). The blot of Fig. 3 includes *P.s.* pv *tomato*; thus, nucleic aicds from *P.s.* pv *tomato* were emcompassed in the invention as filed.

Applicant urges that they introduced the phrase to exclude the nucleic acid taught by Lorang et al. Applicant urges that Lorang shows that *P.s.* pv *tomato* DC3000 has two distinct transcriptional units, including one that comprises a portion of SEQ ID NO:1. Applicant urges that Lorang et al is incorporated by reference into the instant specification and thus is excluded from claim 1 by objected limitation (response pg 6-7).

This is not found persuasive because ncorporated by reference does provide automatic claim limitation or written descriptive support for the idea that the claimed invention does not encompass the nucleic acid of Lorang et al.

5. Claims 1-10 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "wash conditions effective to remove DNA that binds non-specifically to the DNA molecule". Thus, such a phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

6. Claims 1 and 4-10 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:1 or encoding SEQ ID NO:2, does not reasonably provide enablement for nucleic acids that hybridize under conditions of unspecified stringency to SEQ ID NO:1 or for expression of nucleic acids that encode SEQ ID NO:2 or hybridize to SEQ ID NO:1 in plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 June 2002. Applicant's arguments filed 18 April 2003 have been fully considered but they are not persuasive.

Applicant urges that the hybridization conditions have been described in sufficient detail to enable one of skill in the art to isolate the claimed DNA because time temperature and sodium concentration have been recited for the hybridization conditions and because the wash conditions are those effective to remove DNA that binds non-specifically. Applicant urges that one of skill in the art would know how to carry out the wash steps (response pg 7-8).

This is not found persuasive because Applicant has not defined "non-specific"; what is non-specific in one situation may be specific in another. Thus, one of skill in the art could not carry out the wash steps.

Applicant cites Sambrook et al to state that hybridization between DNAs that are 200 nucleotides long are stable while shorter DNAs are not and are thus easily removed during washing. Applicant urges that because SEQ ID NO:1 is longer than 200 nucleotides long, one of skill in the art would understand that post-hybridization wash conditions could be performed as described in Sambrook, and that carrying out that wash would not require undue experimentation (response pg 8).

This is not found persuasive because DNAs of 200 nucleotides would not encode a full-length hypersensitive response elicitor. Applicant has not taught the sequence of any DNA other than SEQ ID NO:1 that hybridizes to SEQ ID NO:1 and that encodes a hypersensitive response elicitor.

Applicant urges that one of skill in the art would know that Southern hybridization of SEQ ID NO:1 to DNAs from other Gram-negative bacteria indicates the presence of HrpW homologs in those species. Applicant cites Guttman et al to also show that HrpW homologs exist in other bacteria, and urges thast Guttman et al supports their claim (response pg 8-9).

This is not found persuasive because Applicant has not taught the sequence of any of these nucleic acids. Hybridization in a Southern blot is not the same thing as teaching sequence. Applicant has not taught the sequence of any DNA other than SEQ ID NO:1 that hybridizes to SEQ ID NO:1 and that encodes a hypersensitive response elicitor.

Applicant urges that one of ordinary skill in the art would have been able to express a protein from a DNA that hybridizes to SEQ ID NO:1 and determine it actually encodes a hypersensitive response elicitor (response pg 9).

This is not found persuasive because it is Applicant's job to teach if DNAs that hybridize to SEQ ID NO:1 encode hypersensitive response elicitor.

Applicant urges that hypersensitive repsonse elictor proteins have a characteristic amino acid composition and properties, including being glycine rich, heat stable, hydrophilic, and a lacking cysteine, as cited in each of Bonas (1994-I), Bonas (1994-II), and Preston et al and that one of ordinary skill in the art would have been able toa ccess whether the proteins enocded by the hybridizing DNA has these properties (response pg 9-10).

This is not found persuasive because Applicant has not demonstrated that the DNAs that hybridize to SEQ ID NO:1 encode proteins that have these properties. Applicant has also not taught the structural elements common to the claimed genes but not to nucleic acids encoding other hypersensitive response elicitors.

7. Claims 1 and 4-10 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 June 2002. Applicant's arguments filed 18 April 2003 have been fully considered but they are not persuasive.

Applicant urges that one of ordinary skill in the art would recognize that Applicant was in possession of isolated DNA molecules from sources other than *P.s.* pv *tomato* that encode HrpW homologs. Applicant urges that they have identified a single species of HrpW by its nucleotide sequence and have shown by Southern hybridization that hrpW is widespread among Gram-negative bacteria (response pg 10).

This is not found persuasive because Southern hybridization is not the same thing as isolation of DNAs. Hybridization is not the same thing as describing the structural elements of DNA. Applicant has not described the structural features of any hypersensitive response elicitor-encoding gene that hybridizes to SEQ ID NO:1 other than SEQ ID NO:1.

Applicant urges that recitation that the protein encodes a hypersensitive response elicitor describes the activity of the encoded protein (response pg 10).

This is not found persuasive because Lilly requires both a structural and functional description. Recitation that the protein encodes a hypersensitive response elicitor only meets the functional requirement. recitation of the structural elements of the claimed DNAs, and a description of the structural elements common to the claimed genes but not to nucleic acids encoding other hypersensitive response elicitors is required.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997) at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.
> ... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.
> ... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1 and 4 are indefinite in their recitation of "wash conditions effective to remove DNA that binds non-specifically to the DNA molecule". It is unclear what those conditions are and it is unclear what level of hybridization is considered non-specific and what level is considered specific.

9. Claims 6-7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are promoters for the expression vector.

Claim Rejections - 35 USC § 102

10. Claims 1 and 4-10 remain rejected under 35 U.S.C. 102(a) as being anticipated by Tabakaki et al (1997, Devel. Plant Biol. 9:392-396). The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 June 2002. Applicant's arguments filed 18 April 2003 have been fully considered but they are not persuasive.

Applicant urges that Tabakaki et al do not teach a nucleic acid as claimed in claim 1 (response pg 10-11).

This is not found persuasive because the wash conditions are not recited in the claims.

11. Claims 1 and 4-10 remain rejected under 35 U.S.C. 102(e) as being anticipated by Bauer et al (US Patent 5,850,015, filed June, 1995). The rejection is repeated for the reasons of record as set forth in the Office action mailed 17 June 2002. Applicant's arguments filed 18 April 2003 have been fully considered but they are not persuasive.

Applicant urges that et al Bauer et al do not teach a nucleic acid as claimed in claim 1 (response pg 11).

This is not found persuasive because the wash conditions are not recited in the claims.

Claim Objections

12. Claims 2-5, 7 and 9-10 are objected to because they have an improper article at the start of the claim.

13. Claims 2-3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form and to address the objection above.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
October 3, 2003